

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 07-046V
Filed: April 20, 2015
(Not to be published)

DIANE DAVIS and ANDREW DAVIS,
as parents of JD, a minor,

Petitioners,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES

Respondent.

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Petitioners' Motion for a Ruling on the
Record; Insufficient Proof of Causation;
Vaccine Act Entitlement; Denial Without
Hearing

DECISION

HASTINGS, *Special Master*

This is an action seeking an award under the National Vaccine Injury Compensation Program ("the Program")¹ on account of an injury to the Petitioners' daughter, JD. For the reasons stated below, I conclude that the Petitioners are not entitled to such an award.

I

THE APPLICABLE STATUTORY SCHEME

Under the National Vaccine Injury Compensation Program ("Program"), compensation awards are made to individuals who have suffered injuries after receiving certain vaccines. There are two separate means of establishing entitlement to compensation. First, if an injury specified in the "Vaccine Injury Table" ("Table"), originally established by statute at §300aa-14(a) and later modified, occurred within the applicable time period after vaccination, as prescribed in the Table, then the injury may be *presumed* to qualify for compensation. §300aa-13(a)(1); §300aa-11(c)(1)(C)(i); §300aa-14(a). If a person qualifies under this presumption, he or she is said to have suffered a "Table Injury."

¹ The applicable statutory provisions governing the National Vaccine Injury Compensation Program are found in 42 U.S.C. §300-10 *et seq.* (2006 ed.). Hereinafter, for ease of citation, all "U.S.C." references will be to 42 U.S.C. (2006 ed.).

Alternatively, if no Table Injury can be shown, the petitioner may gain an award by instead showing that the vaccine recipient's injury was *actually caused* by the vaccination in question. 42 U.S.C. §300aa-13(a)(1); §300aa-11(c)(1)(C)(ii).

II

THE OMNIBUS AUTISM PROCEEDING

This case concerning JD is one of more than 5,400 cases filed under the Program in which it has been alleged that a child's disorder known as "autism," or a similar disorder, was caused by one or more vaccinations. A brief summary of one aspect of that history is relevant to this Decision.

In anticipation of dealing with such a large group of cases involving a common factual issue--*i.e.*, whether vaccinations can cause autism--the Office of Special Masters ("OSM") devised special procedures. On July 3, 2002, the Chief Special Master, acting on behalf of the OSM, issued a document entitled the *Autism General Order # 1*,² which set up a proceeding known as the "Omnibus Autism Proceeding" (OAP). In the OAP, a group of counsel selected from attorneys representing petitioners in the autism cases, known as the Petitioners' Steering Committee ("PSC"), was charged with obtaining and presenting evidence concerning the general issue of whether those vaccines can cause autism, and, if so, in what circumstances. The evidence obtained in that general inquiry was to be applied to the individual cases. (*Autism General Order # 1*, 2002 WL 31696785, at *3, 2002 U.S. Claims LEXIS 365, at *8.)

Ultimately, the PSC elected to present two different theories concerning the causation of autism. The first theory alleged that the *measles* portion of the MMR vaccine can cause autism, in situations in which it was alleged that thimerosal-containing vaccines previously weakened an infant's immune system. That theory was presented in three separate Program "test cases," during several weeks of trial in 2007. The second theory alleged that the mercury contained in the thimerosal-containing vaccines can *directly affect* an infant's brain, thereby substantially contributing to the development of autism. The second theory was presented in three additional "test cases" during several weeks of trial in 2008.

On February 12, 2009, decisions were issued concerning the three "test cases" pertaining to the PSC's *first* theory. In each of those three decisions, the petitioners' causation theories were rejected. I issued the decision in *Cedillo v. HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009). Special Master Patricia Campbell-Smith issued the decision in *Hazlehurst v. HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009).

² The *Autism General Order # 1* is published at 2002 WL 31696785, 2002 U.S. Claims LEXIS 365 (Fed.Cl.Spec.Mstr. July 3, 2002). I also note that the documents filed in the Omnibus Autism Proceeding are contained in a special file kept by the Clerk of this court, known as the "Autism Master File." An electronic version of that File is maintained on this court's website. This electronic version contains a "docket sheet" listing all of the items in the File, and also contains the complete text of most of the items in the File, with the exception of a few documents that are withheld from the website due to copyright considerations or due to § 300aa-12(d)(4)(A). To access this electronic version of the Autism Master File, visit this court's website at www.uscfc.uscourts.gov. Select the "Vaccine Claims" page, then the "Autism Proceeding" page.

Special Master Denise Vowell issued the decision in *Snyder v. HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009).

Those three decisions were later each affirmed in three different rulings, by three different judges of the U.S. Court of Federal Claims. *Hazlehurst v. HHS*, 88 Fed. Cl. 473 (2009); *Snyder v. HHS*, 88 Fed. Cl. 706 (2009); *Cedillo v. HHS*, 89 Fed. Cl. 158 (2009). Two of those three rulings were then appealed to the U.S. Court of Appeals for the Federal Circuit, again resulting in affirmances of the decisions denying the petitioners' claims. *Hazlehurst v. HHS*, 604 F. 3d 1343 (Fed. Cir. 2010); *Cedillo v. HHS*, 617 F. 3d 1328 (Fed. Cir. 2010).

On March 12, 2010, the same three special masters issued decisions concerning three separate "test cases" pertaining to the petitioners PSC's *second* causation theory. Again, the petitioners' causation theories were rejected in all three cases. *King v. HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Dwyer v. HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010). None of the petitioners elected to seek review of any of those three decisions.

III

BACKGROUND

A. Facts

JD and her twin brother were born on November 26, 2001, by cesarean section. (Ex. 3, pp. 10-12.) JD received regular "well child" medical examinations at Renaissance Pediatrics during the first year of life -- at three days of age (11/30/01), six weeks (1/8/02), two months (2/15/02), four months (4/5/02), six-and-one-half months (6/12/02), nine months (9/4/02), and twelve months (12/9/02). (Ex. 4; Ex. 5, pp. 22-28.) At each of these examinations, the notes of her pediatrician include a neurological assessment indicating "within normal limits." During each of these visits, JD received one or more of her routine pediatric vaccinations. (*Id.*, see also Ex. 4.) On December 9, 2002, when JD was twelve months old, she received a varicella vaccination, but not the usual MMR immunization. (Ex. 4; Ex. 5, p. 22.)

After JD's exam at twelve months of age, there are no notations in the pediatric records for the next eighteen months. On May 15, 2004, JD's mother brought her to the pediatrician's office with a complaint of fever and a cough. (Ex. 5, p. 21.) A nurse's note at that time indicates that JD's mother was advised regarding the need for "WCC" -- that is, "well child care" -- and certain immunizations.³ JD's mother expressed concerns "re any other imm[unization]." (*Id.*)

The medical records from Renaissance Pediatrics indicate that JD's next medical examination was administered by Dr. Sharon Tucker, on July 20, 2004, when JD was 2½ years old. (Ex. 5, pp. 11-12.) Her developmental milestones at that time were listed as: "Kicks ball forward, Walks up stairs, Towers 4 cubes, 6 word vocabulary, Points to 2 pictures, 2 word sentences, Uses spoon/fork, Removes garment and Feeds doll." (*Id.*) However, she was not yet

³ The immunizations were listed as "1st MMR, DTaP #4, IPV #3, Hib #4." (Ex. 5, p. 21.)

toilet trained. (*Id.*) Her “mental status” was described as “alert” and “normal,” and her “speech” was “normal,” as were all the other categories listed in her “neurologic” assessment. (*Id.*) Nonetheless, she was referred to an audiologist to evaluate possible “speech delay.” (*Id.*) Dr. Tucker noted that JD’s last set of vaccinations were administered when she was twelve months old, and that JD’s mother again expressed concerns about allowing further vaccinations for her daughter. Dr. Tucker gave Mrs. Davis some explanatory materials about vaccines and obtained a signed statement from her indicating that she understood the potential risks of delaying immunizations. (*Id.*; *see also* Ex. 18, p.18.)

There are no further records from Renaissance Pediatrics until October 7, 2005. (Ex. 17, p. 20.) However, during that interval of more than fourteen months, JD’s parents did consult other health care professionals. On May 3, 2005, Dr. Thomas Montgomery, who specializes in neurodevelopmental pediatrics, performed an evaluation of JD and concluded that she exhibited a communication disorder and sensory integration disorder. (Ex. 6, p. 3; Ex. 15, p. 6.)

Officials from JD’s school district in Virginia administered a variety of tests on May 24, 2005, to evaluate her educational needs. (Ex. 8, pp. 1-20.) JD’s psychological evaluation indicated that her overall cognitive ability was “within the borderline deficient range,” while her overall independent functioning was “within the deficient range.” (*Id.*, p. 2.) Her receptive language ability was adequate, but her expressive language ability was considered “low.” (*Id.*) The school psychologist opined that JD “appears to have global delays at this time.” (*Id.*, p. 3.) JD’s speech and language evaluation showed that “all language skills appeared to be severely delayed.” (*Id.*, p. 11.) Based on this assessment, JD was found to be eligible for special educational services. (*Id.*, pp. 11-20; *see also* Ex. 9, for subsequent educational evaluations.)

On August 22, 2005, JD was examined by Mary Megson, M.D. (Ex. 7, pp. 5-9.) Dr. Megson opined that JD suffered from high-functioning ASD (*i.e.*, autism spectrum disorder.) (*Id.*, p. 9.) Based on that assessment, Dr. Megson administered various dietary supplements and other treatments. (*Id.*, pp. 10, 12.)

On October 7, 2005, JD returned to Renaissance Pediatrics to receive well child care. (Ex. 17, p. 20.) At that visit, Dr. Dionne Harewood noted JD’s recent autism diagnosis, and the multiple nutritional supplements prescribed by Dr. Megson. (*Id.*)

On June 11, 2007, officials representing JD’s public school system concluded that she suffered from various developmental delays, and should continue to receive special education services. (Ex. 9, pp. 33-34.)

Virginia Proud, M.D., who specializes in genetics at the Eastern Virginia Medical School in Norfolk, examined JD on July 11, 2012. (Ex. 10, pp. 1-5.) Dr. Proud reported that JD “had behavioral issues and communication disorders and has a diagnosis of autism spectrum * * * She also has what is described as a complex I mitochondrial homoplasmic mutation.” (*Id.*, p. 4.) The case history recorded by Dr. Proud includes the following:

At six months of age [JD] did not lose skills but after her immunizations, she had fever, crying, and GI problems. She, however, unlike her brother, did not lose skills. She continued to do well developmentally * * * She rolled over at 4 months, sat at 6 months, pulled to stand at 9 months, crawled at 9 months, cruised at 12 months, walked at 13 months * * * first word however not until 18 months.

She currently is talking well. She is going into the fifth grade and does have an IEP and is mainstreamed. She does get occupational and speech therapy.

(Ex. 10, p. 3.) Dr. Proud opined in a report dated July 18, 2012, that JD “has a probably Mitochondrial Disorder with molecularly confirmed Complex-I defect.” (Ex. 10, p. 1.)

B. Procedural History

Diane and Andrew Davis (hereinafter “Petitioners”) filed a “Short-Form Autism Petition for Vaccine Compensation” on January 19, 2007. That filing constitutes an allegation that their daughter, JD, developed an autism spectrum disorder, or a similar neurodevelopmental disorder, that was caused by either the measles-mumps-rubella vaccination (“MMR”), or by the thimerosal ingredient in other vaccinations covered by the Program. See *Autism General Order # 1*, 2002 WL 31696785, at *4, *8 (Fed. Cl. Spec. Mstr. July 3, 2002).

On January 31, 2007, individual proceedings in this case were stayed pending the conclusion of the Omnibus Autism Proceeding (“OAP”). (Order, filed Jan. 31, 2007.) As the OAP neared completion, Petitioners were directed to file all of the medical records relevant to their claim, pursuant to 42 U.S.C. §300aa-11(c)(2). (Order, filed Oct. 15, 2009.) Petitioners requested, and were allowed, a 90-day enlargement of time to file those records. (Order, filed March 29, 2010.) Petitioners filed a Notice regarding the format of the medical records on April 13, 2010, along with a Statement of Completion indicating that all the available relevant records were included. (Notice and Statement, filed April 13, 2010.) On April 19, 2010, Petitioners filed Exhibits 1-9, in the form of a “compact disc.”

Respondent filed a Statement, in response, indicating that, based on Exhibits 1-9, Respondent was unable to determine the date of onset of JD’s condition, or whether Petitioners’ claim had been timely filed. (Statement, filed May 27, 2010.) Respondent also alleged that there were significant gaps in the medical record and specific records that were lacking. (*Id.*)

Petitioners did not file any supplemental information, or any response to Respondent’s Statement, for eighteen months. On November 10, 2011, I filed an Order noting the outcome of the OAP test cases, as described above in Section II, and directing Petitioners to inform the court if they wished to proceed with their case. If so, Petitioners were ordered to file, within 30 days, an amended petition that was fully compliant with § 300aa-11(c), and which clearly explained their theory of vaccine causation in this case. (Order, filed Nov. 10, 2011.) There was no response.⁴ On December 13, 2011, I filed an Order to Show Cause, indicating that this case would be dismissed if Petitioners failed to file an appropriate response to my Order of November 10, 2011. On January 6, 2012, I granted Petitioners’ request for a 30-day extension of time to file an appropriate response. Instead, on February 6, 2012, Petitioners’ counsel, Herbert Waichman, filed a motion to withdraw as counsel of record,⁵ and another request for additional time. Further enlargements of time were allowed, thereafter, until Mr. Waichman was ultimately relieved of his duties as counsel. (See Orders filed Feb. 7, Feb. 23, and May 21, 2012, and Jan. 3, 2013.) On January 3, 2013, I filed an Order directed to the now *pro se* Petitioners, ordering

⁴ Petitioners have never filed an amended petition in response to this order.

⁵ It is notable that the Motion to Withdraw as Attorney of Record, filed on Feb. 2, 2012, included the following statement: “In petitioner’s counsel’s view, there is no reasonable basis to proceed forward with petitioner’s case. To do so would, in counsel’s view, be wasteful of Program resources.”

Petitioners to file, within 30 days, an amended petition that was fully compliant with §300aa-11(c), and which clearly explained their theory of vaccine causation in this case.

On January 28, 2013, Petitioners filed a Statement indicating that they were trying to replace their counsel so that they could continue pursuit of their claim. Petitioners were allowed additional enlargements of time to file all of the medical records required by §300aa-11(c), and a Statement of Completion. (*See* Orders filed Feb. 6, May 8, and July 1, 2013.) Each of these orders allowing enlargements of time included the following instruction: “You must file within 90 days of the date of this Order all available medical records of [JD’s] well-child visits between twelve and thirty one months of age; records pertaining to the diagnosis of [JD’s] ASD, any records discussing the cause of [JD’s] ASD, and specialist treatment records.” (*Id.*, pp. 1-2.) However, nothing was filed.

On September 10, 2013, I filed another Order to Show Cause, stating that Petitioners’ claim would be dismissed if they failed to file the required medical records within 30 days. Petitioners filed a Response on October 3, 2013, requesting additional time to comply with the Order to Show Cause. Additional time was allowed. (Order, filed Oct. 24, 2013.)

On January 10, 2014, Petitioners filed a Motion to Substitute Attorney Patricia Finn in place of the *pro se* Petitioners. That Motion was granted on January 17, 2014, and Petitioners were again ordered to file the required medical records. On April 1, 2014, Petitioners filed Exhibit 10, a medical record of geneticist Virginia Proud, M.D. Petitioners also filed a separate Statement of Completion indicating that all of the relevant medical records had been filed. (Statement, filed April 1, 2014.)

On May 19, 2014, Respondent filed a Supplemental Rule 4(c) Report and Motion to Dismiss, which again detailed the alleged failure by Petitioners to file all of the documentation required by § 300aa-11(c). Respondent also objected that Petitioners had never attempted to establish that their Petition was timely filed, or filed an amended petition articulating Petitioners’ theory of vaccine causation. (Motion to Dismiss, filed May 19, 2014, p. 12.)

On June 3, 2014, counsel for both parties participated in a status conference to discuss identification of medical records relevant to Petitioners’ claim. (*See* Order, filed June 4, 2014.) Petitioners were instructed to file a status report within 60 days describing their efforts to file those records. Petitioners were also instructed to provide basic information regarding their claim in that status report, including: “the vaccination that allegedly injured their daughter, the date it was administered, the first symptoms of the injury, and the date when those symptoms appeared.” (*Id.*) Petitioners filed a status report on July 31, 2014, which did not contain the required information, but argued that an additional ninety days were needed to “provide the Court with an amended complaint setting forth the allegations of the petition and responding to the Court’s June 4th Order.” (Status Report, filed July 31, 2014.)

Respondent filed a Response, on July 31, 2014, noting that Petitioners had been provided with an explicit list of medical records that remained outstanding. However, Respondent also contended that this case lacked “reasonable basis” to proceed, and should, therefore, be dismissed immediately. (Response, filed July 31, 2014.) Nonetheless, I decided to grant Petitioners’ request for additional time. (Order, filed Aug. 7, 2014.)

On October 30, 2014, Petitioners filed various medical records, consisting of Exhibits 11 through 20, along with a request for additional time to file the other outstanding records and to provide Petitioners' answers to the specific questions propounded by the court. On October 31, 2014, I filed an Order allowing a two-week enlargement of time. That Order included the following instructions:

Petitioners' counsel shall study the recently-filed medical records and determine whether this case was timely-filed. On or before November 13, 2014, petitioners' counsel shall file the outstanding medical records, and a status report addressing the timeliness issue. That status report shall specifically identify: 1) the vaccination that allegedly injured J.D., 2) the date it was administered, 3) the first symptoms of the injury, and 4) the date when those symptoms appeared.

(Order, filed Oct. 31, 2014.)

Petitioners filed various medical records on November 13, 2014, identified as Exhibits 19, 20, and 21.⁶ Also on November 13, 2014, Petitioners filed a Status Report addressing the issues set forth in my previous orders, as follows:

With regards to the questions set out by the Court in the June 4, 2014 Order it is petitioner's position that the varicella vaccine administered on December 9, 2002 is the vaccine that allegedly caused JD's injuries. JD's speech issues were first noted at a well child visit on July 20, 2004 when the minor petitioner was 2 years 8 months old. *** The petition in this case was filed on January 19, 2007 and the onset of symptoms did not occur until July 2004, therefore this petition is timely and should not be dismissed.

Thus, Petitioners now allege specifically that JD suffered an injury caused by the varicella vaccination administered on December 9, 2002, and that the first symptom of that injury appeared about eighteen months later, in July of 2004. Petitioners also explained the change in their theory of the case, as follows:

Although this case was originally filed in the OAP, this was an error. The two theories presented in the OAP cases were (1) that the measles portion of the measles, mumps, rubella vaccine could cause ASDs and (2) that the mercury contained in thimerosal-containing vaccines could directly affect an infant's brain, thereby substantially contributing to the causation of ASD. JD has never received an MMR vaccination and the varicella vaccination alleged to have caused JD's injuries does not contain thimerosal.

(Status Report, filed Nov. 13, 2014.)

On November 18, 2014, I filed an Order, which contained the following specific instructions:

In Petitioners' status report filed on November 13, 2014, Petitioners assert that (1) the varicella vaccine of December 9, 2002, caused J.D.'s injury, but that (2) the first symptoms of that injury occurred when J.D. was around 2½ years to 2 years and eight months old, which would have been between April and July of

⁶ Unfortunately, exhibit numbers 20 had previously been assigned to different exhibits.

2004. However, that assertion leaves a gap of about a year and one half between the vaccination in question and the onset of symptoms. Petitioners are hereby given 90 days from the date of this order in which to file an expert report that draws a causal connection between that varicella vaccination and J.D.'s autism.

(Order, filed Nov. 18, 2014.) A status conference was convened on December 3, 2014, with the participation of counsel for both parties. During that conference, I notified Petitioners' counsel that, given Petitioners' representations in the status report filed in this case on November 13, 2014, I had grave doubts whether there exists a "reasonable basis" for spending further attorney time or costs on this case. (Order, filed Dec. 3, 2014.)

In response to my Order filed on November 18, 2014, Petitioners did not file an expert report to support their claim that the varicella vaccination caused an injury to JD. Instead, on February 16, 2015, Petitioners filed a "Motion for Ruling on the Record," alleging again that JD's varicella vaccination of December 9, 2002, caused her "behavioral issues, communication disorders, and autism." Accordingly, I will now rule on the existing record.

C. Issues for decision

The timeliness of this Petition need not be resolved. Instead, the only issue that I will decide is whether the varicella vaccination administered to JD on December 9, 2002, *caused* JD's autism and related conditions.

III

DISCUSSION

In order to qualify for an award under the Program, Petitioners must prove either: 1) that JD suffered a Table Injury--*i.e.*, an injury falling within the Vaccine Injury Table--corresponding to one of her vaccinations, or 2) that she suffered an injury that was actually caused by a vaccine. *See* 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1).

Petitioners do not claim that JD suffered a "Table Injury," and in my examination of the filed medical records, I did not find in the record any evidence that JD suffered a "Table Injury."⁷

The legal standard to establish "actual causation" of an injury by a vaccine requires that a petitioner must present "1) a medical theory causally connecting the vaccination and the injury; 2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and 3) a showing of a proximal temporal relationship between vaccination and injury." *Althen v. HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Under the statute, a petitioner may not be given a Program award based solely on the petitioner's claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. 42 U.S.C. § 300aa-13(a)(1). In this case, the records do

⁷ The "varicella" vaccine that is alleged to be the cause of JD's condition, is listed on the Vaccine Injury Table, but there are no "Table Injury" conditions identified regarding the varicella vaccine. 42 C.F.R. § 100.3(a)(X).

not contain a medical expert's opinion or any other evidence indicating that JD's autism, or any other condition, was caused by her varicella vaccine. No physician expressed such an opinion in the records that I reviewed, and the petitioners have not pointed to any place in the records where any physician stated such an opinion. Here, because the medical *records* do not support the petitioners' claim, a medical *opinion* must be offered in support. Petitioners, however, have offered no such opinion.

Further, none of the three prongs of the *Althen* standard to establish causation have been satisfied. Petitioners have not offered a medical theory causally connecting the varicella vaccination to autism or any other condition from which JD suffers; nor have Petitioners presented a logical sequence of cause and effect showing that the varicella vaccine caused an injury to JD. Finally, Petitioners have failed to even try to demonstrate that the eighteen-month interval between the administration of JD's varicella vaccination and the alleged date of onset of JD's symptoms constitutes the "proximal temporal relationship" that is required by the third prong of the *Althen* standard.

IV

CONCLUSION

It is, of course, tragic that JD suffers from significant neurological problems. She and her family are certainly deserving of sympathy for those difficulties. However, under the law I can authorize compensation only if a medical condition or injury either falls within one of the "Table Injury" categories, or is shown by medical records or competent medical opinion to be vaccine-caused. No such proof exists in the record before me. Accordingly, it is clear from the record in this case that Petitioners have not demonstrated either that JD suffered a Table Injury, or that her autism or any other condition was "actually caused" by a vaccination. Therefore, I have no choice but to hereby DENY this claim. In the absence of a timely-filed motion for review of this decision (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accord with this decision.

George L. Hastings, Jr.
Special Master